



One Test to Rule Them All?

Dr. Leslie Fischer, J.D., Ph.D.

USPTO Eligibility Forum, Alexandria VA, January 20, 2015

The views presented here are my own, and do not necessarily reflect the views of my employer, Novartis Pharmaceuticals Corporation.

The Alice 2-Step ...

- (1) Is the claim directed to an ineligible concept (natural phenomena, natural law or abstract idea), and if so,
- (2) Does the claim to contain an “inventive concept” sufficient to “transform” the ineligible concept into a patent-eligible application of the concept?

An “inventive concept” can be identified using various “tests” derived from *Chakrabarty*, *Mayo*, *Myriad*, *Alice*, *Funk Brothers*, etc., e.g.,

- the claim includes an inventive contribution
- the claimed subject matter has a distinctive name, character, or use
- the claim is directed to a solution of a technological problem
- the claim as a whole demonstrates a new or enlarged range of utility from that of the judicial exception (JE)
- the claim, element-by-element or as a whole, includes a structural or functional difference over the JE

...Is More of a 1-Step

+ a categorization error

- If the claim is directed to a JE (Step 2A), but in step two we determine that the claim contains an inventive concept (Step 2B) that renders the claim eligible, there must have been a categorization error in step one.

See, Eclipse IP LLC v. McKinley Equip. Corp., C.D. Cal., No. 2:14-cv-00154-GW-AJW, September 4, 2014

- Step 2A “markedly different characteristics” (MDC) test determines whether a natural-product based (NPB) limitation is a JE.
- Step 2B seeks an inventive concept by asking if the claim recites additional elements that amount to significantly more than the JE.
 - Gives applicants with NPB limitations two bites at the apple of eligibility.
- But, currently impossible for claims reciting NPB JE(s), and no other element, to satisfy “significantly more” under Step 2B, because Step 2B literally requires “additional elements”.

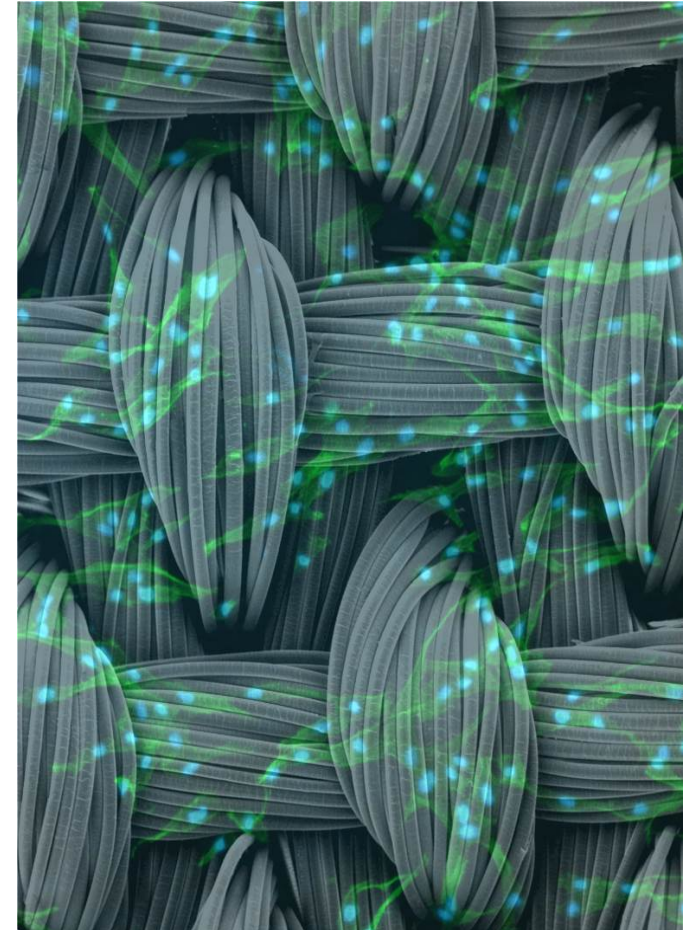
Example 9, Claim 5

USPTO Analysis

- A composition comprising a population of isolated pacemaker cells in a biocompatible three-dimensional scaffold.
- Can be implanted into a patient where they facilitate faster tissue regeneration than when the cells are implanted sans scaffold.
- Step 2A: placing cells in scaffold doesn't result in the cells or the scaffold having any different characteristics from naturally-occurring cells or scaffolds. No MDC.

Step 2B: cells can be used with other scaffolds and *vice versa*, the composition can only be used for cardiac repair, the specificity of the scaffold, provision of a technological improvement (i.e., the field of regenerative medicine). Significantly more.

- Compare to analysis of *Funk Brothers* facts in Example 6, claim 1 of Guidance. No additional elements = no significantly more.



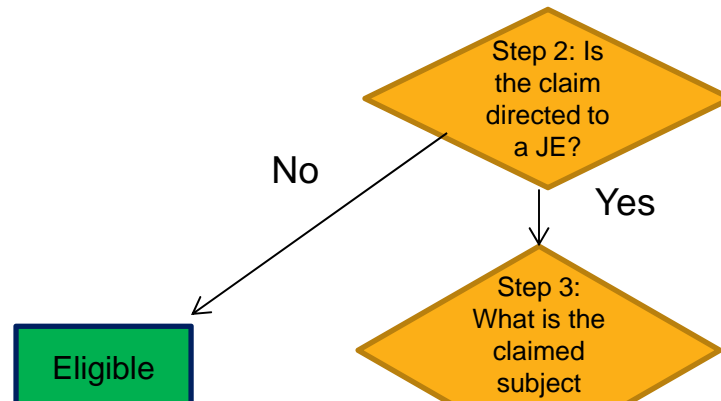
Example 9, Claim 5

Something doesn't add up

- Guidance (Section I.A.3.a) correctly notes that the proper comparison is the mixture (cells in matrix) to its components (cells, matrix).
- What went wrong?
- Categorization error in Step 2A: The claimed compositions can be implanted directly into a patient where they *facilitate faster tissue regeneration* than the cells alone. Composition has MDC and is not a JE. Step 2A satisfied. **Eligible.**
- Step 2B is correct (“additional elements” required): USPTO misapplied step 2B. Composition does not have MDC. No additional elements in the claim, thus nothing “significantly more.” **Ineligible.**
- Section 2B is incorrect (“additional elements” not required): USPTO correctly analyzed with typical process-based case law tests, e.g., field of use, recitation of claim limits with specificity, etc. **Eligible.**
- ...or....

One Test Doesn't Rule Them All

- Process: seek additional elements, features, steps; useful applications of ideas; specificity; transformation, etc., to find significantly more than a JE.
- Products: seek changes in structure, function, properties; expansion in the range of utility; a distinctive name, character, or use, etc., to find significantly more than a JE.



"Additional elements" is not an appropriate test for product/composition claims.

Improvement: "Does the claim, as a whole, contain any element, or combination of elements (including a combination of JEs), that is sufficient to ensure that the claim amounts to significantly more than the JE?"